

510(k) Summary

510(k) Number: K06XXXX
Company: Arthrex, Inc.
Address: 1370 Creekside Blvd., Naples, FL 34108-1945
Telephone: (239) 643-5553
Facsimile: (239) 598-5508
Contact: Ann Waterhouse

Device Name: Arthrex Bio-Compression Family
Classification: Screw, Fixation, Bone
Product Code: HWC
Predicate Devices:

Description:

The Arthrex Bio-Compression Family is currently comprised of enhanced Poly(L-Lactide) or PLLA implants in various lengths and diameters. They are offered sterile.

Indications for Use:

The Arthrex Bio-Compression Screw is intended for fixation of fractures, osteotomies and arthrodesis in:

- Carpal, metacarpal, and small hand bone
- tarsal and metatarsals
- phalanges
- Intra-articular fractures
- ankle
- proximal and distal humerus
- proximal and distal radius
- proximal and distal ulna
- osteochondral fixation and fractures
- Osteochondritis Dissecans
- Fixation of fractures and osteotomies about the knee
- Oblique fractures of the fibula
- Reconstructive surgeries of the foot
- malleolar fixation

where size of offered implant is patient appropriate.

Technical Differences:

The basis for substantial equivalence is in supporting the use of your device in the same manner as that of a competitor. The in house test data provided, as well as articles cited, support the use of the Arthrex Bio-Compression Family in the indications sought.

Substantial Equivalence:

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device for the previously cleared indications for use. The Arthrex Bio-Compression Family of Implants does not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials used in construction of these devices are well characterized and have been used in predicate devices with similar indications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

Arthrex, Inc.
% Ms. Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K060478
Trade/Device Name: Arthrex Bio-Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 20, 2006
Received: April 21, 2006

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Ann Waterhouse, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

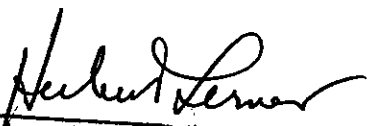
Device Name:

Indications For Use:

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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510(k) Number K060478

510(k) Number (if known): K060478

Device Name: Arthrex Bio-Compression Screw

Indications for Use:

The Arthrex Bio-Compression Screw is intended for fixation of fractures, osteotomies and arthrodesis in:

- Carpal, metacarpal, and small hand bone
- tarsal and metatarsals
- phalanges
- Intra-articular fractures
- ankle
- proximal and distal humerus
- proximal and distal radius
- proximal and distal ulna
- osteochondral fixation and fractures
- Osteochondritis Dissecans
- Fixation of fractures and osteotomies about the knee
- Oblique fractures of the fibula
- Reconstructive surgeries of the foot
- malleolar fixation

where size of offered implant is patient appropriate.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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